DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 8 2003

Mr. Doug Harding
Vice President
Quality Systems/Regulatory Affairs
Applied Biotech, Inc,
10237 Flanders Court
San Diego, CA 92121

Re: k024332
Trade/Device Name: SureStep™ Propoxyphene (PPX) Drug Screen Test Cassette/Dipstick Formats
Regulation Number: 21 CFR 862.3700
Regulation Name: Propoxyphene test system
Regulatory Class: Class II
Product Code: JXN
Dated: December 23, 2002
Received: December 26, 2002

Dear Mr. Harding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K024332

Device Name: **SureStep™ Propoxyphene (PPX) Drug Screen Test Cassette/Dipstick Formats**

Indications For Use:

CASSETTE FORMAT

The Applied Biotech SureStep™ Drug Screen Propoxyphene (PPX) Drug Screen Test (Dipstick) is an in vitro screen test for the rapid detection of Propoxyphene (PPX) in human urine at a cut-off of 300 ng/ml. This test kit is used to obtain a visual, qualitative result and is intended for professional use.

The SureStep™ Drug Screen Propoxyphene (PPX) Drug Screen Test provides only a preliminary test result. A more specific alternate chemical methodology, such as GC/MS, must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

DIPSTICK FORMAT

The SureStep™ Propoxyphene (PPX) Drug Screen Test (Dipstick) is a modification to Applied Biotech's SureStep™ Propoxyphene Drug Screen test with the following difference:

The SureStep™ Propoxyphene (PPX) Drug Test strip is operated in a vertical orientation (dipstick), whereas the predicate devices are horizontal (cassette)

(Division Sign-Off)
Division of Cli...
510(k) Number K024332

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)